IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARRAY BIOPHARMA INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ALEMBIC PHARMACEUTICALS LIMITED and ALEMBIC PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Array BioPharma, Inc. ("Plaintiff" or "Array"), for its Complaint against Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. (collectively "Defendants" or "Alembic"), alleges as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiff against Defendants for infringement of United States Patent Nos. 9,314,464 (the "'464 patent"), 9,850,229 (the "'229 patent"), 10,005,761 (the "'761 patent"), 9,562,016 (the "'016 patent"), 9,598,376 (the "'376 patent"), and 9,980,944 (the "'944 patent") (the "Mektovi Patents").

2. This action arises out of Alembic Pharmaceuticals Limited's submission of Abbreviated New Drug Application ("ANDA") No. 217678 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Array's MEKTOVI product prior to the expiration of the Mektovi Patents.

THE PARTIES

3. Plaintiff Array is a corporation organized and existing under the laws of Delaware, having a place of business at 3200 Walnut Street, Boulder, Colorado 80301.

4. On information and belief, defendant Alembic Pharmaceuticals Limited is an Indian corporation, having its principal place of business at Alembic Road, Vadodara - 390 003, Gujarat, India.

5. On information and belief, defendant Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 750 Route 202, Bridgewater, New Jersey 08807. On information and belief, Alembic Pharmaceuticals, Inc., is a wholly-owned subsidiary of Alembic Global Holding SA, which is a wholly-owned subsidiary of Alembic Pharmaceuticals Limited. On information and belief, Alembic Pharmaceuticals, Inc. is the U.S. agent for Alembic Pharmaceuticals Limited.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Defendants.

8. This Court has personal jurisdiction over Alembic Pharmaceuticals, Inc. by virtue of the fact that Alembic Pharmaceuticals, Inc. is a Delaware corporation.

9. On information and belief, Alembic Pharmaceuticals, Inc. is registered to conduct business in the State of Delaware (File No. 5197177) and has the following registered agent in the State of Delaware: National Registered Agents, Inc., 160 Greentree Dr., Suite 101, Dover, Delaware 19904.

10. This Court has personal jurisdiction over Alembic Pharmaceuticals Limited by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiff, including in the State of Delaware. In particular, this suit arises out of Alembic Pharmaceuticals Limited's submission of

ANDA No. 217678 seeking FDA approval to sell 15 mg binimetinib tablets (the "Alembic Generic Tablets"), prior to the expiration of the Mektovi Patents, throughout the United States, including in the State of Delaware.

11. On information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. are agents of each other and/or work in concert with each other in the development, regulatory approval, marketing, sale, and/or distribution of generic drugs, including the Alembic Generic Tablets, throughout the United States, including into the State of Delaware. On information and belief, Alembic Pharmaceuticals, Inc. is the U.S. agent for Alembic Pharmaceuticals Limited.

12. On information and belief, Alembic Pharmaceuticals Limited, directly or through its subsidiary Alembic Pharmaceuticals, Inc., manufactures, markets, imports, and sells generic drugs for distribution throughout the United States, including in the State of Delaware. *See* https://www.alembicusa.com/corporate-profile.aspx ("Alembic Pharmaceuticals, Inc., is a subsidiary of Alembic Pharmaceuticals Ltd.") (last visited September 7, 2022); *id*. ("Alembic has identified the United States as the key market for expansion and development.").

13. On information and belief, if ANDA No. 217678 is approved, Alembic Generic Tablets will be, among other things, marketed and distributed by Defendants in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

14. Defendants' infringing activities with respect to their submission of ANDA No. 217678 and their intent to commercialize and sell Alembic Generic Tablets has led and/or will lead to foreseeable harm and injury to Plaintiff Array, which is incorporated in the State of Delaware.

15. On information and belief, Defendants maintain substantial, systematic and continuous contacts throughout the United States, including with the State of Delaware. Alembic's website states that "[t]he company now sells more than 100 products in the United States, representing more than 400+ SKUs under its own label. Alembic intends to launch 15 to 20 products each year over the next 3 years." https://www.alembicusa.com/corporate-profile.aspx (last visited September 7, 2022).

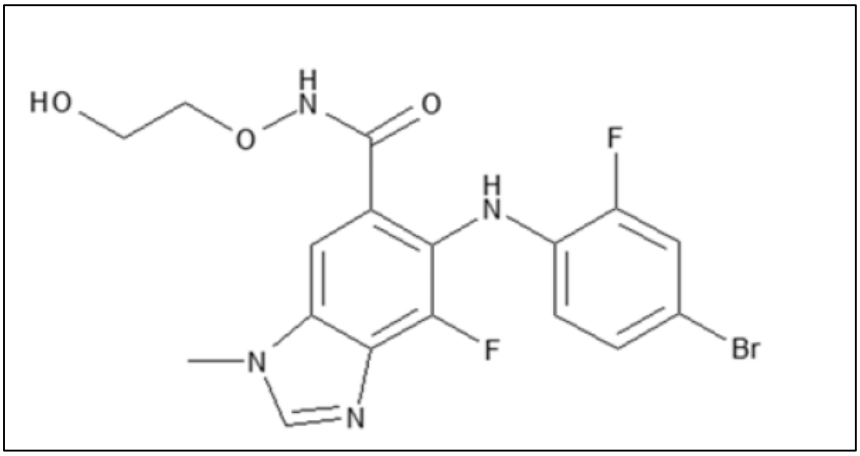
16. On information and belief, Defendants sell their products directly to wholesalers, retail drug store chains, drug distributors, mail order pharmacies and other direct purchasers as well as customers that purchase their products indirectly through the wholesalers, including independent pharmacies, non-warehousing retail drug store chains, managed health care providers and other indirect purchasers, throughout the United States, including in the State of Delaware.

17. In the alternative, this Court has jurisdiction over Alembic Pharmaceuticals Limited under Federal Rule of Civil Procedure 4(k)(2). Alembic Pharmaceuticals Limited has contacts with the United States by, *inter alia*, having filed its ANDA with the FDA.

18. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

19. The active ingredient in Array's MEKTOVI product is binimetinib, a reversible inhibitor of mitogen-activated extracellular signal regulated kinase 1 (MEK1) and MEK2 activity, having the chemical name 5-[(4-bromo-2-fluorophenyl)amino]-4-fluoro-N-(2-hydroxyethoxy)-1-methyl-1H-benzimidazole-6-carboxamide. The chemical structure of binimetinib is shown below:



20. The FDA-approved Prescribing Information states that MEKTOVI is indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

21. MEKTOVI tablets for oral use contain 15 mg of binimetinib with the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate (vegetable source), and colloidal silicon dioxide. The coating contains polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, ferric oxide yellow, and ferrosoferric oxide.

The ’464 Patent

22. On August 19, 2016, the United States Patent and Trademark Office (“USPTO”) issued the ’464 patent, titled “Compounds and Compositions as Protein Kinase Inhibitors.” The ’464 patent is duly and legally assigned to Array. A copy of the ’464 patent is attached hereto as Exhibit A.

23. The ’464 patent contains claims directed to methods of treating a B-Raf protein kinase mediated cancer with specific compounds, including in combination with binimetinib.

The ’229 Patent

24. On December 26, 2017, the USPTO issued the ’229 patent, titled “Compounds and Compositions as Protein Kinase Inhibitors.” The ’229 patent is duly and legally assigned to Array. A copy of the ’229 patent is attached hereto as Exhibit B.

25. The ’229 patent contains claims directed to methods of treating melanoma using a combination of encorafenib and a MEK inhibitor, such as binimetinib.

The ’761 Patent

26. On June 26, 2018, the USPTO issued the ’761 patent, titled “Compounds and Compositions as Protein Kinase Inhibitors.” The ’761 patent is duly and legally assigned to Array. A copy of the ’761 patent is attached hereto as Exhibit C.

27. The ’761 patent contains claims directed to methods of treating cancer with encorafenib, including in combination with binimetinib.

The ’016 Patent

28. On February 7, 2017, the USPTO issued the ’016 patent, titled “Preparation of and Formulation Comprising a MEK Inhibitor.” The ’016 patent is duly and legally assigned to Array. A copy of the ’016 patent is attached hereto as Exhibit D.

29. The ’016 patent contains claims directed to crystalline binimetinib and pharmaceutical compositions comprising crystalline binimetinib.

The ’376 Patent

30. On March 21, 2017, the USPTO issued the ’376 patent, titled “Preparation of and Formulation Comprising a MEK inhibitor.” The ’376 patent is duly and legally assigned to Array. A copy of the ’376 patent is attached hereto as Exhibit E.

31. The ’376 patent contains claims directed to methods of treating a cancer in a patient in need thereof using crystalline binimetinib.

The ’944 Patent

32. On May 29, 2018, the USPTO issued the ’944 patent, titled “Preparation of and Formulation Comprising a MEK inhibitor.” The ’944 patent is duly and legally assigned to Array. A copy of the ’944 patent is attached hereto as Exhibit F.

33. The ’944 patent contains claims directed to methods of treating melanoma using crystallized binimetinib.

Orange Book Listing for MEKTOVI

34. Array holds approved New Drug Application (“NDA”), No. 210498, for 15 mg binimetinib tablets, which Array sells under the registered name MEKTOVI. As stated in Array’s FDA approved label for MEKTOVI (“Mektovi Label”), the drug is indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

35. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the Mektovi Patents are listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) with respect to MEKTOVI.

36. The Orange Book lists the expiration date for the ’464 patent as July 4, 2031; the expiration date for the ’229 patent as August 27, 2030; the expiration date for the ’761 patent as August 27, 2030; the expiration date for the ’016 patent as October 18, 2033; the expiration date for the ’376 patent as October 18, 2033; and the expiration date for the ’944 patent as October 18, 2033.

37. The Orange Book lists four additional patents for MEKTOVI: U.S. Patent Nos. 7,777,050 (expiring March 13, 2023); 8,178,693 (expiring March 13, 2023); 8,193,229

(expiring March 13, 2023); and 8,513,293 (expiring March 13, 2023). Defendants' Paragraph IV notice does not address these four patents.

Alembic's ANDA

38. By letter dated August 15, 2022, and received by Plaintiff on August 16, 2022 (the "Alembic Notice Letter"), Defendants notified Array that Alembic Pharmaceuticals Limited had submitted ANDA No. 217678 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Alembic Generic Tablets prior to the expiration of the Mektovi Patents.

39. On information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and submission of ANDA No. 217678.

40. The Alembic Notice Letter states that ANDA No. 217678 contains a Paragraph IV certification under 21 U.S.C. § 355(j), alleging that the claims of the Mektovi Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of the Alembic Generic Tablets.

41. The Alembic Notice Letter states that through ANDA No. 217678, Alembic seeks to obtain approval from the FDA to market binimetinib tablets, 15 mg, prior to the expiration of the Mektovi Patents.

42. The Alembic Notice Letter contains an Offer of Confidential Access to ANDA No. 217678, pursuant to Section 355(j)(5)(C)(i)(III), offering confidential access to Alembic's ANDA No. 217678.

43. Attached to the Alembic Notice Letter was Alembic's Detailed Statement ("Alembic's Detailed Statement") alleging the factual and legal bases for why Alembic contends

that the Mektovi Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Alembic Generic Tablets.

44. Alembic's Detailed Statement asserts that Alembic Generic Tablets will not infringe any claims of the Mektovi Patents.

45. Alembic's Detailed Statement does not include any argument concerning the validity or enforceability of the Mektovi Patents.

46. On information and belief, upon approval of ANDA No. 217678, Alembic will distribute Alembic Generic Tablets in the United States, including in Delaware.

COUNT I
(Infringement of the '464 Patent by Alembic)

47. The allegations of paragraphs 1-46 above are repeated and re-alleged as if set forth fully herein.

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Limited's submission of ANDA No. 217678 seeking approval to market Alembic Generic Tablets was an act of infringement of at least one claim of the '464 patent entitling Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 217678 be a date which is not earlier than the expiration date of the '464 patent.

49. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 217678 copies the indication in Array's Mektovi Label and states that Alembic Generic Tablets are indicated for the treatment, in combination with encorafenib, of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

50. Defendants had knowledge of the '464 patent when they submitted ANDA No. 217678 to the FDA.

51. On information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Alembic Generic Tablets with the proposed labeling.

52. The use of Alembic Generic Tablets in accordance with and as directed by Alembic's proposed labeling will infringe at least claim 10 of the '464 patent.

53. On information and belief, Defendants intend to actively induce infringement of at least claim 10 of the '464 patent.

54. On information and belief, Defendants intend to contribute to the infringement of at least claim 10 of the '464 patent.

55. On information and belief, Defendants know that Alembic Generic Tablets and the proposed labeling are especially made or adapted for use in infringing at least one claim of the '464 patent and that the Alembic Generic Tablets and the proposed labeling are not suitable for any substantial noninfringing use.

56. The foregoing actions by Defendants constitute and/or would constitute infringement of at least claim 10 of the '464 patent, active inducement of infringement of at least claim 10 of the '464 patent, and/or contribution to the infringement by others of at least claim 10 of the '464 patent.

57. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '464 patent. Plaintiff has no adequate remedy at law.

COUNT II
(Infringement of the '229 Patent by Alembic)

58. The allegations of paragraphs 1-57 above are repeated and re-alleged as if set forth fully herein.

59. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Limited's submission of ANDA No. 217678 seeking approval to market Alembic Generic Tablets was an act of infringement of at least one claim of the '229 patent entitling Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 217678 be a date which is not earlier than the expiration date of the '229 patent.

60. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 217678 copies the indication in Array's Mektovi Label and states that Alembic Generic Tablets are indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

61. Defendants had knowledge of the '229 patent when they submitted ANDA No. 217678 to the FDA.

62. On information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Alembic Generic Tablets with the proposed labeling.

63. The use of Alembic Generic Tablets in accordance with and as directed by Alembic's proposed labeling will infringe at least claim 1 of the '229 patent.

64. On information and belief, Defendants intend to actively induce infringement of at least claim 1 of the '229 patent.

65. On information and belief, Defendants intend to contribute to the infringement of at least claim 1 of the '229 patent.

66. On information and belief, Defendants know that Alembic Generic Tablets and the proposed labeling are especially made or adapted for use in infringing at least one claim of

the ’229 patent and that the Alembic Generic Tablets and the proposed labeling are not suitable for any substantial noninfringing use.

67. The foregoing actions by Defendants constitute and/or would constitute infringement of at least claim 1 of the ’229 patent, active inducement of infringement of at least claim 1 of the ’229 patent, and/or contribution to the infringement by others of at least claim 1 of the ’229 patent.

68. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the ’229 patent. Plaintiff has no adequate remedy at law.

COUNT III
(Infringement of the ’761 Patent by Alembic)

69. The allegations of paragraphs 1-68 above are repeated and re-alleged as if set forth fully herein.

70. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Limited’s submission of ANDA No. 217678 seeking approval to market Alembic Generic Tablets was an act of infringement of at least one claim of the ’761 patent entitling Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 217678 be a date which is not earlier than the expiration date of the ’761 patent.

71. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 217678 copies the indication in Array’s Mektovi Label and states that Alembic Generic Tablets are indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

72. Defendants had knowledge of the ’761 patent when they submitted ANDA No. 217678 to the FDA.

73. On information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Alembic Generic Tablets with the proposed labeling.

74. On information and belief, Defendants intend to actively induce infringement of at least claim 11 of the ’761 patent.

75. The use of Alembic Generic Tablets in accordance with and as directed by Alembic’s proposed labeling will infringe at least claim 11 of the ’761 patent.

76. On information and belief, Defendants intend to contribute to the infringement of at least claim 11 of the ’761 patent.

77. On information and belief, Defendants know that Alembic Generic Tablets and the proposed labeling are especially made or adapted for use in infringing at least one claim of the ’761 patent and that the Alembic Generic Tablets and the proposed labeling are not suitable for any substantial noninfringing use.

78. The foregoing actions by Defendants constitute and/or would constitute infringement of at least claim 11 of the ’761 patent, active inducement of infringement of at least claim 11 of the ’761 patent, and/or contribution to the infringement by others of at least claim 11 of the ’761 patent.

79. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the ’761 patent. Plaintiff has no adequate remedy at law.

COUNT IV
(Infringement of the ’016 Patent by Alembic)

80. The allegations of paragraphs 1-79 above are repeated and re-alleged as if set forth fully herein.

81. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Limited's submission of ANDA No. 217678 seeking approval to market Alembic Generic Tablets was an act of infringement of at least one claim of the '016 patent entitling Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 217678 be a date which is not earlier than the expiration date of the '016 patent.

82. Defendants had knowledge of the '016 patent when they submitted ANDA No. 217678 to the FDA.

83. On information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Alembic Generic Tablets which will infringe at least claim 3 of the '016 patent.

84. The foregoing actions by Defendants constitute and/or would constitute infringement of at least claim 3 of the '016 patent.

85. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '016 patent. Plaintiff has no adequate remedy at law.

COUNT V
(Infringement of the '376 Patent by Alembic)

86. The allegations of paragraphs 1-85 above are repeated and re-alleged as if set forth fully herein.

87. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Limited's submission of ANDA No. 217678 seeking approval to market Alembic Generic Tablets was an act of infringement of at least one claim of the '376 patent entitling Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective

date of approval for ANDA No. 217678 be a date which is not earlier than the expiration date of the ’376 patent.

88. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 217678 copies the indication in Array’s Mektovi Label and states that Alembic Generic Tablets are indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

89. Defendants had knowledge of the ’376 patent when they submitted ANDA No. 217678 to the FDA.

90. On information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Alembic Generic Tablets with the proposed labeling.

91. The use of Alembic Generic Tablets in accordance with and as directed by Alembic’s proposed labeling will infringe at least claim 1 of the ’376 patent.

92. On information and belief, Defendants intend to actively induce infringement of at least claim 1 of the ’376 patent.

93. On information and belief, Defendants intend to contribute to the infringement of at least claim 1 of the ’376 patent.

94. On information and belief, Defendants know that Alembic Generic Tablets and the proposed labeling are especially made or adapted for use in infringing at least one claim of the ’376 patent and that the Alembic Generic Tablets and the proposed labeling are not suitable for any substantial noninfringing use.

95. The foregoing actions by Defendants constitute and/or would constitute infringement of at least claim 1 of the ’376 patent, active inducement of infringement of at least

claim 1 of the ’376 patent, and/or contribution to the infringement by others of at least claim 1 of the ’376 patent.

96. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the ’376 patent. Plaintiff has no adequate remedy at law.

COUNT VI
(Infringement of the ’944 Patent by Alembic)

97. The allegations of paragraphs 1-96 above are repeated and re-alleged as if set forth fully herein.

98. Pursuant to 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Limited’s submission of ANDA No. 217678 seeking approval to market Alembic Generic Tablets was an act of infringement of at least one claim of the ’944 patent entitling Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 217678 be a date which is not earlier than the expiration date of the ’944 patent.

99. On information and belief, the proposed labeling and/or package insert submitted with ANDA No. 217678 copies the indication in Array’s Mektovi Label and states that Alembic Generic Tablets are indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

100. Defendants had knowledge of the ’944 patent when they submitted ANDA No. 217678 to the FDA.

101. On information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Alembic Generic Tablets with the proposed labeling.

102. The use of Alembic Generic Tablets in accordance with and as directed by Alembic's proposed labeling will infringe at least claim 1 of the '944 patent.

103. On information and belief, Defendants intend to actively induce infringement of at least claim 1 of the '944 patent.

104. On information and belief, Defendants intend to contribute to the infringement of at least claim 1 of the '944 patent.

105. On information and belief, Alembic knows that Alembic Generic Tablets and the proposed labeling are especially made or adapted for use in infringing at least one claim of the '944 patent and that the Alembic Generic Tablets and the proposed labeling are not suitable for any substantial noninfringing use.

106. The foregoing actions by Defendants constitute and/or would constitute infringement of at least claim 1 of the '944 patent, active inducement of infringement of at least claim 1 of the '944 patent, and/or contribution to the infringement by others of at least claim 1 of the '944 patent.

107. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '944 patent. Plaintiff has no adequate remedy at law.

COUNT VII
(Alembic Pharmaceuticals, Inc.'s Inducing of Infringement by Alembic Pharmaceuticals, Limited)

108. The allegations of paragraphs 1-107 above are repeated and re-alleged as if set forth fully herein.

109. On information and belief, Alembic Pharmaceuticals, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Alembic Pharmaceuticals, Limited of ANDA No. 217678 to the FDA, knowing of the Mektovi Patents.

110. The submission of ANDA No. 217678 by Alembic Pharmaceuticals, Limited constituted direct infringement of the Mektovi Patents under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Alembic Pharmaceuticals, Inc. induced the infringement of the Mektovi Patents by actively and knowingly causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 217678 to the FDA knowing that the submission of ANDA No. 217678 would constitute direct infringement of the Mektovi Patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

A. A judgment that Alembic Pharmaceuticals Limited's submission of ANDA No. 217678 to the FDA was an act of infringement of the '464, '229, '761, '016, '376, and '944 patents and that Defendants' making, using, offering to sell, selling or importing Alembic Generic Tablets prior to the expiration of the '464, '229, '761, '016, '376, and '944 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '464, '229, '761, '016, '376, and '944 patents;

B. A judgment that defendant Alembic Pharmaceuticals, Inc.'s knowing and purposeful activities causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 217678, knowing that its submission would constitute direct infringement, induced infringement of the '464, '229, '761, '016, '376, and '944 patents;

C. A judgment that the effective date of any FDA approval for Defendants to make, use offer for sale, sell, market, distribute, or import Alembic Generic Tablets be no earlier than the latest of the dates on which the '464, '229, '761, '016, '376,

and ’944 patents expire, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

D. A permanent injunction enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing Alembic Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expirations of the ’464, ’229, ’761, ’016, ’376, and ’944 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

E. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiff to an award of their reasonable attorneys’ fees for bringing and prosecuting this action;

F. An award of Plaintiff’s costs and expenses in this action; and

G. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiff

OF COUNSEL:

Aaron Stiefel
Daniel P. DiNapoli
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
(212) 836-8000

David C. McMullen, PhD
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue NW
Washington, DC 20001
(202) 942-5000

September 28, 2022